REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1, 2, 4, 5, 9, 17, 23, and 31 are amended.

Claims 19, 20, 21, 22, 25, 26, 27, 28, 29, and 30 are withdrawn.

Claims 1-18, 23, 24 and 31 are under examination.

II. Amendments

1. The term "derivative" has been removed from claims.

2. Claims 2 and 31 are corrected.

3. Claim 1 is amended to recite "An isolated or purified nucleic acid . . . ." (page 10)

IV. Other Issues

1. Contrary to the examiner's assertion, the term "creatinine deiminase" is correct. "Creatinine deiminase" is correct, because the enzyme cleaves an imino group (NH) and not an amino group (NH_2) from creatinine (see claim 2). To provide further evidence, please find enclosed the specification sheet of "Creatinine Deiminase Microbial" from Sigma-Aldrich (Exhibit A). The examiner is requested to issue a corrected Office Action using the correct spelling of the enzyme in the application.

2. Regarding the Examiner's statement that claim 2 is confusing, since by definition creatinine deiminase does not deaminate cytosine, the claim is to define that the polypeptide having creatinine deminase activity does **not** deaminate cytosine. This is not contradictory or unclear, because it is known that the substrate specificity of enzymes is rarely absolute, i.e., enzymes exhibit an activity not only on compounds known to be substurates but also on other compounds, which may be structurally related to the known substrates. In fact, creatinine deiminases exist which exhibit both creatinine deiminase activity and cytosine deaminiase activity, while other creatinine deiminases exhibit creatinine deiminase activity only.

3. An English translation of the abstract and claims of the Japanese citation (05-275,482) is submitted concurrently, as a Supplemental Information Disclosure Statement.

4. The disclosure satisfies the enablement and written description criteria of 35 U.S.C. 112.

Page	Lines	Comment
5	9-16	"molecules can be non-coding (e.g. a probe, antisense, or ribozyme molecules) . . . or functional . . . can hybridize with a nucleic acid sequence shown SEQ ID No: 1 or complement thereof under mildly stringent or highly stringent conditions."
	18-20	"at least 50% homology"
	27	"encodes a protein having creatinine deiminase activity."
7	FIG. 4 Legend	production of ammonia and n-methylhydontoin
9 10	30-32 12-13	describes functional test for isolated nucleic acids within the scope of the invention.
13	26-37	hybridizes (antisense), probes, stringency
15	12-21	homology described
17-18		functional tests of encoded polypeptide.
21	23-36	"Production and hybridizing of a specific probe against the creatinine deiminase coding gene (*cdi* gene)
22	14-16	colony hybridization using labeled probe
23	6-11	sequence comparisions, FIG. 7

Those of skill in the art know how to hybridize and to check whether there is at least 50% homology between nucleic acid sequences. Tests for function of the encoded polypeptides are described and are routine (e.g. pages 17-18). Citations given in the specification to the methods in the literature are well known in the art. The claims do not relate all sequences that hybridize to SEQ ID NO: 1, only those that are functional (encode creatinine deiminases) and are at least 50% homologous. The inventor had possession of all sequences that hybridize to SEQ ID NO: 1 and have the function of creatinine deiminiase because there is a clear concept and enablement disclosed.

Contrary to the examiner's assertion on page 4 of the Office Action, the number of "possible nucleotide substitutions, deletions and/or additions" is limited -- by the specification defining substitutions (pages 15, lines 29-35; 16, lines 5-30), by the hybridization requirement, and by the functional requirement -- it must encode a creatinine deiminase. In response to the examiner's comments on the Federal Circuit decisions: (1) at least one species of the claimed genus is disclosed by sequence SEQ ID NO: 1); and (2) common function is disclosed and easily tested by disclosed methods.

The rest of the examiner's requirements on page 5 are not required by law.

The Wands factors do not prohibit routine experimentation. Hybridization, determination of homology, and tests for creatinine deiminase function are not only routine, but are disclosed in the specification as shown at least in the summary table herein.

There is no need to identify specific regions of the protein structure because if there is no function as claimed, a nucleic acid molecule will not be within the scope of the claims regardless of **why** there is no function. The inventors are entitled to protection against infringers who deviate from SEQ ID NO: 1 but still have a creatinine deiminase (Office Action pages 4-5).

Applicants request allowance of the pending claims. No fees are believed due at this time, however, please charge any deficiencies or credit any overpayments to deposit account number 12-0913 with reference to our attorney docket number (35635-94974).

Respectfully submitted,

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